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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,797	06/12/2002	Herman Jan Tijmen Coelingh Bennink	97473 US	8680

7590 12/03/2003

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	11

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,797	COELINGH BENNINK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,10-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,10-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on September 11, 2003 have been received and entered into the application. Accordingly, claims 1, 3, 5-9 and 15-18 have been cancelled. The rejection of original claims 10 and 11 of record under 35 U.S.C. 112 second paragraphs made on last Office Action is hereby expressly withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claims 10 and 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 11 recite the limitation "said sequentially administered doses" in claims 10 and 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

Claims 2, 4, 10-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodgen (WO 93/21927) of record in view of Schoonen et al. (XP-002124156) of record and Hamersma et al. (U.S.Patent No. 5,854,235).

Hodgen teaches a method for minimizing menstrual bleeding irregularities in individuals using progestin-only pharmaceutical preparation, such as contraceptive, comprising administering anti-progesterone such as Org 31710. (abstract, page 5, lines 20-30, page 7, lines 20-32). Hodgen teaches that anti-porgestin above can be administered monthly, or at other intermittent intervals. (page 9, lines 32-36). Hodgen teaches the intervals and number of doses can vary and a suitable regimen is having the anti-progestin administered every thirty days, every sixty days or every ninety days and in the case of contraceptives, the anti-progestin can be administered on the twenty-eighth day of each cycle. (page 10, lines 5-20).

Schoonen teaches the anti-progestinic activity of Org 33245 is compared to that of Org 31710, in vitro and in vivo, it is shown that the Org 33245 is more active than the Org 31710. (abstract, page 164, table, right hand column, lines 18-24, page 167, right-hand column, lines 1-7).

Hamersma et al. teach that Org 33245 is useful in contraception and it exhibit the normal activities known for anti-progestogen such as treatment of menstrual disorders and hormone dependent tumors. (column 1, lines 1-8, column 12, lines 33-36).

The differences between Hodgen and Applicants' claims are the employment of specified anti-progestagen, Org 33245 and the specific dosing schedule set forth in claim 4.

It would have been obvious to one of ordinary skill in the art to modify Hodgen's method to employ Org 33245 in place of Org 31710 because Schoonen teaches Org 33245 is compared to that of Org 31710, in vitro and in vivo, it is shown that the Org 33245 is more active than the Org 31710 and because Hemersma et al. teach that Org 33245 is exhibits the normal activities known for anti-progestogen such as treatment of menstrual disorder and useful for contraception.

One of ordinary skill in the art would have been motivated to modify Hodgen's method to employ Org 33245 in place of Org 31710 to achieve expected benefit of increased activity of anti-progestin therapy for the contraception and decreased in menstrual disorder such as bleeding. Absent any evidence to contrary, there would have been reasonable expectation of successfully employing Org 33245 in Hodgen's method in hormone replacement therapy, e.g. contraception and bleeding irregularies.

The dosing schedule set forth in claim 4 is obvious because the intervals can vary with concurrent medication therapy and each optimum dosing frequency are determined by the practitioners; further 1-7 days during a cycle of 28-32 day administration is obvious since they are all within the conventional dosing regimen of contraceptives.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed September 11, 2003 have been fully considered but they are not persuasive. Applicants' argue that '927 patent only describes the protracted administration of progestogen with administration of compound on the 28th or 30th day of the treatment cycle and does not teach Org 33245 to be administered intermittently, the intermission between each pair of sequentially administered dosage units of anti-protestogen being more than one day. This is not persuasive because '927 teach the anti-progestins can be administered in intermittent intervals including monthly which would be greater than one day. (page 9, lines 34-36). Applicants' next argue that '235 does not teach or disclose treatment regimen or dosage schedules therefore the '235 patent does not teach or disclose a method of the treatment of contraception or hormone replacement therapy using Org 33245 with the specified dosage regimen. This is not persuasive because '235 patent teaches Org 33245 is useful in contraception and it exhibits the normal activities known for anti-progestogen including treatment of menstrual disorder and hormone dependent tumors which is relevant teaching of Applicant's claimed effect. This teaching that Org 33245 exhibit the normal activities known for anti-progestogen including treatment of menstrual disorder and hormone dependent tumors and useful in contraception would motivate one of ordinary skill in the art to use the dosing regimen of anti-progestogen taught by '927 for the employment in contraception or to minimize uterine bleeding treated with hormone replacement therapy of anti-progestin. Applicants finally argue that a person skilled in the art would have no teaching that Org 33245 would have a sufficient duration of action

such that it would be suitable for the purposes of the present invention (or in fact that Org 33245 would be preferable over Org 33628) and that Applicants' invention, illustrated that Org 33245 is preferable over Org 33628 in an intermittent range. This is not persuasive because Org 33628 and Org 31710 are both taught to be useful for the intermittent dosage regimen by Hodgen (page 7, lines 20-25,page 9, lines 32-35). Given that anti-progesten compounds (Org 31710 and Org 33628) are taught to be effective, it would have logically followed that compounds structurally, therapeutically similar (e.g. Org 33245) would also be effective which would have motivated the skilled artisan to select such compounds from those known. Applicants' allegation that it is illustrated that Org 33245 is preferable over Org 33628 in an intermittent range is not supported by a data. It is suggested, to advance the prosecution of the subject application, that a side-by-side comparison of Org 33245 and Org 33628 be performed and results submitted per Rule 1.132 for review by the Patent Office.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
November 28, 2003

12/1/03